



## High flex total knee arthroplasty – A prospective, randomized study with results after 10 years

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This prospective randomized study compares the long term results between total knee arthroplasty with a mobile bearing high flex and a fixed bearing posterior stabilized knee (LPS) in 39 patients. The Hospital for Special Surgery score (HSS) was calculated and radiographs in AP and lateral view were analyzed after a minimum follow-up of 10 years. No significant differences between the two groups were found. The mean HSS-score was 90.67 ( $\pm$  5.75) for LPS group patients and 90.83 ( $\pm$  8.57) points for the high flex group patients. Three patients in the high flex group had undergone a reoperation on their knee. One knee was revised for painful mid-flexion instability and the others for symptomatic aseptic loosening of the tibial prosthesis. Based on these and other findings, the use of a high flex knee system may be seriously re-considered. Further studies are required to evaluate possible long-term adverse effects of high flex knee systems.

**Keywords:** total knee arthroplasty ; high-flex knee ; mobile bearing ; flexion ; range of motion.

### INTRODUCTION

The high flex total knee arthroplasty (TKA) was developed for patients requiring a deeper flexion range up to 150° for reasons of profession, culture or religion. The high-flex knee (NexGen LPS Flex mobile, Zimmer, Warsaw, USA) was specially designed to prevent increasing wear and to maintain

knee stability in comparison to the regular posterior stabilised (PS) knee (NexGen LPS). An additional 2 mm bone cut from the posterior femoral condyles leads to a greater offset of the posterior condyles. The tibial insert has an anterior recess to avoid patellar tendon impingement during deep flexion. Furthermore, it is a mobile bearing system that allows an internal and external rotation of 25° each. The design leads, in theory, to reduced contact stresses at the different interfaces and decreased polyethylene wear rate. Rotational mobility of the bearing surface might also optimize the tibio-femoral alignment, which could lead to a higher stability and decreased anterior knee pain (11). Wohlrab *et al*

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previously reported the short- and mid-term results (3 months, 3 years and 5 years follow-up) of a randomised clinical and radiological study comparing the results after TKA using the NexGen Flex mobile knee versus the NexGen LPS knee (20). Three and 5 years postoperatively, there were no significant differences between both groups for the Hospital for Special Surgery score (HSS), nor for the radiological results. A clear advantage of the mobile bearing knee prostheses could not be reflected in the clinical results up to 5 years after surgery. Other studies had even shown a higher complication rate postoperatively using mobile bearing systems. Ridgeway *et al* observed early coronal plane instability and knee pain in 25 cases within 2 years postoperatively (15). Further, subluxation, dislocation, increasing wear rate and stress shielding were observed (15).

The aim of this study was to compare clinical and radiographic long-term results at least 10 years after TKA using a high-flex knee (NexGen Flex mobile) versus a regular PS knee (NexGen LPS) to evaluate the possible advantages or disadvantages of high-flex knee systems and to investigate if one design may be more effective in preventing implant loosening.

## PATIENTS AND METHODS

In 2000, we included 60 patients who underwent a TKA in a prospective randomized study. They were preoperatively divided into two groups using a randomization list. A NexGen LPS implant (Zimmer Inc., Warsaw, USA) was implanted in 30 patients; the remaining 30 patients received the high-flex NexGen LPS Flex mobile-bearing knee (Zimmer Inc.). All patients in this study were diagnosed with unilateral degenerative arthritis, had a body mass index (BMI) less than 30, no previous joint infection, a varus deformity of less than 10° or a valgus deformity less than 5°. Preoperatively, we recorded patients' data (age, gender, height, body weight) as well as the Hospital for Special Surgery score (HSS) (9). The patients' demographic data are shown in Table I. All surgeries were done by two well-trained surgeons. The surgeons were equally familiar with both knee systems and their learning curves were completed. The operative procedures were similar in both groups. In all procedures, a mid vastus approach was used. The patella was resurfaced and all implants were cemented in all cases. Tourniquet was used in each patient. Drains

were removed 48 h after surgery. The rehabilitation program during admission was the same for both groups and the patients were discharged 5-7 days after surgery.

At the time of the follow-up after a minimum of 10 years (10.8 years,  $\pm 0.8$ ), 3 patients (all in the high flex group) had died for causes unrelated to the operation, and 15 (8 in the LPS group, 7 in the high flex group) were lost to follow-up. Three patients of the high flex group had undergone a reoperation on their knee. This left a total of 22 LPS knees and 17 high flex knees for final evaluation including the HSS-score and radiographs (AP view in extension and lateral view in maximal flexion). Using the radiographs and the Knee Society Roentgenographic Evaluation and Scoring System (3), radiolucent lines and the maximal knee flexion were determined. The data were analysed with Student's t-test. The significance level was set at  $p < 0.05$ .

## RESULTS

Preoperatively there were no relevant differences between the two groups. The mean HSS score of LPS group patients was 48.63 ( $\pm 8.47$ ) points and that of the high-flex group patients was 54.38 ( $\pm 6.29$ ) points. In the subgroups of the HSS score, there were no differences except for the category pain which was less in the high-flex group. There were also no relevant differences in the maximal knee flexion between the two groups preoperatively (Table I).

At the 10-year follow-up, no significant differences between the two groups were found regarding clinical and radiographic results. The mean HSS-score of LPS group patients was 90.67 ( $\pm 5.75$ ) versus 90.83 ( $\pm 8.57$ ) for the high flex group patients. In the LPS group there was a marginally higher subtraction rate of the HSS score as result of an extension lag of 5° in 2 patients and a necessity of using crutches by 4 patients related to coxarthrosis and unsteady gait in polyneuropathy (Table I). Using the Knee Society Roentgenographic Evaluation and Scoring System, there was one patient of the LPS group with radiolucent lines smaller than 10 mm in zones 1 and 4 of the tibia in the AP view without clinical symptoms and a HSS score of 91. In the high flex group 1 patient showed radiolucent lines smaller than 5 mm in zone 1 of the tibia in the AP view and femoral in zone 1 in the lateral view. There

Table I. — Demographic data, HSS score and radiographic evaluation preoperatively and 10 years after surgery

	Preoperatively				10 years			
	LPS		High Flex		LPS		High Flex	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
N (joints)	30	–	30	–	22	–	17	–
Age (years)	65.5	9.1	66.5	5.3	74.9	7.7	73.1	10.5
Male	12	–	14	–	10	–	8	–
Female	18	–	16	–	12	–	9	–
BMI	24.4	6.6	24.1	5.9	30.1	–	29.1	–
HSS-Score								
Pain	3.0	4.8	8.0	3.1	28.0	3.2	27.5	5.0
Function	12.8	3.2	14.1	2.2	22.0	0.0	21.8	0.6
Range of motion	13.4	2.0	13.7	1.6	14.7	1.5	14.7	1.2
Muscle strength	9.2	1.4	9.9	0.5	9.9	0.5	10.0	0.0
Flexion deformity	6.3	2.9	5.0	2.6	7.7	3.7	7.5	4.0
Instability	8.2	1.2	7.4	1.1	9.3	1.0	9.5	0.9
Subtraction	4.4	2.1	3.8	2.2	0.9	1.2	0.2	0.6
Total HSS	48.6	8.5	54.4	6.3	90.7	5.8	90.8	8.6
Radiological evaluation								
Maximal flexion	105.6	17.8	108.5	14.8	114.4	9.4	114.8	10.1

were also no symptomatic signs with a high HSS score of 93.

One patient of the high flex group had a painful mid flexion instability that needed to be revised after 5 years. Because of symptomatic aseptic loosening of the cemented tibial prosthesis, two others high flex knees were revised after 7 and 8 years. In the AP view tibial radiolucent lines were found in zone 1 and 5 in one knee and the other showed a progressive lucency in zone 1 (Fig. 1).

## DISCUSSION

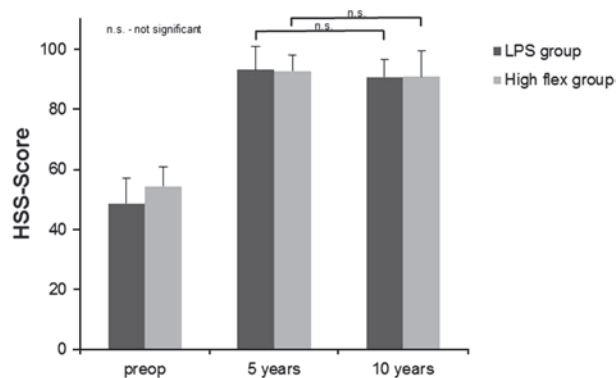
The high flex total knee arthroplasty with a mobile bearing system was developed to increase the ROM and to optimize the tibio-femoral alignment. This self-alignment should theoretically decrease the wear rate with a positive effect in preventing early implant loosening. Several studies had shown that these advantages are not reproducible in clinical practice in considering short and mid-term results (11,15,19,20). In the present study, we compared the clinical and radiographic long-term results of

the high flex knee (NexGen Flex mobile, Zimmer, USA) and regular PS knee (NexGen LPS, Zimmer, USA) after a minimum of 10 years. Wohlrab *et al* already reported the short- and mid-term results (3 months, 3 years and 5 years follow up) of both study groups (20). Three months postoperatively, there were better results in scores for pain, ROM (122.5° vs. 107.3°), as well as in the overall HSS (87.2 vs. 82.7 points) in the high-flex group. Three and 5 years postoperatively, there were no significant differences between both groups for the Hospital for Special Surgery score (HSS), nor for the radiological results (20). After ten years, we again found no differences between patients with these implant designs with respect to pain, function, range of motion, muscle strength, flexion deformity and instability. Especially the theoretical advantages of high flex knee systems, namely the ROM (114.40 vs. 114.83), joint stability and function were similar. Comparing the results, 5 and 10 years postoperatively, for both groups there were no significant differences in the total HSS score and in the maximal knee flexion (Fig. 2 & 3). Several studies have

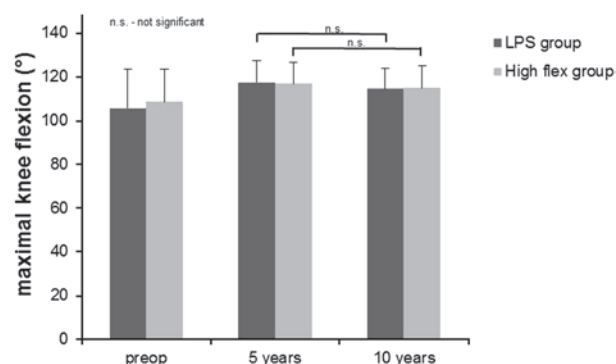


**Fig. 1.** — High flex knee with aseptic loosening of the cemented tibial baseplate after 8 years (Tibial radiolucency in zone 1 using the Knee Society Roentgenographic Evaluation and Scoring System).

reported an improved ROM comparing standard designs with high flex designs within the first two years after surgery (1,5,8,18). On the other hand, the majority of prospective randomized trials showed no significant difference comparing high flex knee system to conventional knee system (6,10,12,20). It is assumed that the preselection of patients with at least 90° of flexion and not excessively high BMIs is jointly responsible for the clinical results in respect to function and flexion (12). Ranawat (14) and Ritter (16) stated that the preoperative ROM is the most important factor for the postoperative knee flexion unaffected by the implant design. However, our study has shown that the physiological ROM (up to 150°) is not achieved using either a PS knee or high flex knee. While instability and subluxation are typical complications especially with mobile bearing systems (15,17), we just revised one patient of the high flex group for painful mid flexion instability after 5 years. It is postulated that mobile



**Fig. 2.** — Total HSS scores of the NexGen LPS (LPS group) versus NexGen LPS Flex mobile (High flex group), pre- and postoperatively.



**Fig. 3.** — Radiographically measured maximal knee flexion of the NexGen LPS (LPS group) versus NexGen LPS Flex mobile (High flex group).

bearing systems could reduce contact stresses at the different interfaces, resulting in a decreased wear rate, with a positive effect in preventing early implant loosening (2,4,13). Our long-term results cannot confirm this advantage. There were three patients with radiolucent lines at the tibial surface. Two of them had undergone a reoperation for symptomatic aseptic loosening of the cemented tibial prosthesis after 7 and 8 years. Han *et al* reported a 38% aseptic loosening rate in 72 high-flexion knees at a mean follow-up of 32 months (7). Early loosening of the femoral component in high flexion knees was a predominant problem associated with weight-bearing in maximum flexion. We were not able to confirm this association of femoral loosening with higher flexion; we observed more tibial than

femoral loosening in our series. One explanation could be that only the tibial plate was cemented, but the central stud was not. Further histological examinations of revised knees are necessary to support this hypothesis.

The major weakness of this study is the number of lost patients in each group. Fifteen knees (25%) were lost to the final follow-up despite extensive efforts to contact all patients. However, this is an inherent difficulty in long-term studies (15). As a consequence the number of patients included in such long-term studies should be increased right from the beginning.

In summary, this prospective, randomized controlled trial demonstrated no benefit to the high flex knee system versus a regular PS knee up to 10 years after surgery. Using both knee systems the achieved knee flexion was considerably increased compared to the old gold standard of 90° flexion. The physiological ROM (up to 150°) was not achieved using either one of these implants. Three patients in the high flex group had to be revised for reasons of instability and aseptic implant loosening.

In view of our long term results without clear benefits and of the higher incidence of implant loosening, the use of a high-flex knee system should be seriously reconsidered.

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